

Engel *et al.*—08/468,145—
Client/Matter—098501-0217506

I. CLAIM AMENDMENTS

20. (Currently Amended) A method for the preparation of a sterile Cetorelix lyophilizate, said method comprising the steps of

(a) dissolving Cetorelix having the amino acid sequence of
AC-D-Nal(2)-D-pCl-Phe-D-Pal(3)-Ser-Tyr-D-Cit-Leu-Arg-Pro-D-Ala-NH₂ (SEQ ID
NO: 1) in aqueous acetic acid to form a solution, wherein the acetic acid has a pH range
between 2.5-3.0,

(b) diluting said solution with water for injection,
(c) adding bulking agent to the solution, and
(d) sterile filtering, dispensing into injection vials and lyophilizing the solution,
thereby obtaining a sterile Cetorelix lyophilizate.

21. (Previously Presented) The method according to claim 20, wherein the bulking agent used is a hexitol.

22. (Previously Presented) The method according to claim 21 wherein the hexitol is selected from the group consisting of mannitol, glucitol, sorbitol, D-sorbitol, dulcitol, allitol, iditol, urea or sodium chloride in an amount from 10 – 500 parts by weight per one part by weight Cetorelix.

23. (Previously Presented) The method according to claim 20, wherein 1 part by weight of cetorelix acetate is dissolved in 100-10,000 parts by weight of a 30% strength (w/w) acetic acid solution and diluted with water to 3% strength aqueous acetic acid, and wherein the bulking agent is mannitol.